DEC 2 7 2002

EXHIBIT 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K021987

1. Submitter's Identification:

S&S Par Scientific
10625 Telge Road
Houston, Texas 77095

Date Summary Prepared: June 14, 2002

Contact: Mr. Fred Sopenoff
Manager, Radiology Division

2. Name of the Device:

ParComPlast™ Compensating Filter for Radiation Therapy

3. Predicate Device Information:

1. K#000137, Enhanced Compensating Filter, Computerized Medical Systems, Inc., St. Louis, MO

2. K#010172, Lead Blocks, Arplay Medical S.A., Cote D'or, France

4. Device Description:

ParComPlast™ is a solid block of polyurethane and fillers. It is intended to be used as material for construction of beam intensity modifiers for radiation therapy treatment. In use, a block of ParComPlast™ is placed into the holder of a milling machine such as described in our 510(k) K#883317, or, in similar machines produced by other manufacturers: a beam modifying filter is milled out using the x, y, z data supplied by either the planning computer or our contouring system. Once the filter is machined, it is mounted to the shadow tray plate using screws or double face tape and the plate is inserted into the holder on the accelerator for the patient's treatment.

5. Intended Use:

To shape the beam for a radiation therapy source.

6. **Comparison to Predicate Devices:**

1. K#000137, Enhanced Compensating Filter, Computerized Medical Systems, Inc., St. Louis, MO, which is compensator milled directly from aluminum or brass block, and

2. K#010172, Lead Blocks, Arplay Medical S.A., Cote D'or, France, which are lead blocks of varying sizes and heights to build compensator filters.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Product testing contained in this 510(k) submission demonstrated that ParComPlast™ can be used as compensator material on a similar level as aluminum (is used clinically). There is no difference in material behavior as materials used in the predicate devices.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The subject device, ParComPlast™ Compensating Filter for Radiation Therapy has the same intended use and similar characteristics as the predicate devices. Non-clinical testing supplied in our 510(k) submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new questions of safety or effectiveness. Thus, ParComPlast™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2002

S & S Par Scientific
% Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K021987
Trade/Device Name: ParComPlast™ Compensating Filter for Radiation Therapy
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: 90 IXI
Dated: October 8, 2002
Received: October 10, 2002

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K021987

Device Name: ParComPlast™ Compensating Filter for Radiation Therapy

Indications For Use:

To shape the beam from a radiation therapy source.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021987